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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,316	06/26/2001	Jennifer L. Hillman	PF-0213-2 DIV	1945

7590 09/29/2003

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PATENT DEPARTMENT
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EXAMINER	
CARLSON, KAREN C	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/892,316	HILLMAN ET AL.	
	Examin r	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1653	

-- The MAILING DATE of this communicati n appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 25-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-15 and 25-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claims 16-24 and 30-44 have been canceled. Claims 1-15 and 25-29 are pending.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, 9, 11, and 12, drawn to nucleic acid encoding SEQ ID NO: 1, classified in class 536, subclass 23.1.

II. Claim 8, drawn to Transgenic organism comprising nucleic acid encoding SEQ ID NO: 1, classified in class 800, subclass 2.

III. Claims 10, drawn to antibody against SEQ ID NO: 1, classified in class 530, subclass 387.1.

IV. Claims 13-15, drawn to a method for detecting nucleic acid encoding SEQ ID NO: 1 via hybridization, classified in class 435, subclass 6.

V. Claim 25, drawn to a method for screening a compound that binds to SEQ ID NO: 1, classified in class 435, subclass 7.1.

VI. Claim 26, drawn to a method for screening a compound that modulates the activity of SEQ ID NO: 1, classified in class 435, subclass 7.1.

VII. Claim 27, drawn to a method for screening a compound that changes the expression of a nucleic acid that encodes to SEQ ID NO: 1, classified in class 435, subclass 6.

VIII. Claim 28, drawn to a method for assessing toxicity of a compound via a nucleic acid that encodes to SEQ ID NO: 1, classified in class 435, subclass 6.

IX. Claim 29, drawn to method of diagnosing disease via antibody against SEQ ID NO: 1, classified in class 530, subclass 387.1.

The inventions are distinct, each from the other because of the following reasons:

The nucleic acid of Invention I and the antibody of Invention III are related by virtue of the protein that is encoded by the nucleic acid and necessary for the production of the

antibody. However, the nucleic acid itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these Inventions are distinct.

The nucleic acid of Invention I and the transgenic organism of Invention II are related because the organism comprises the nucleic acid.. However, the products are wholly different and therefore these Inventions are patentably distinct.

The antibody of Invention III is not used to make the transgenic organism of Invention II and both are distinct products in structure and in function. Therefore, Inventions II and III are patentably distinct.

Inventions I and Inventions IV, VII, and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in the methods of any one of IV, VII, or VIII, or in the recombinant production of protein.

The nucleic acid of Invention I is not used in the methods of Inventions V, VI, or IX. Therefore, Invention I is patentably distinct from Inventions V, VI, and IX.

The transgenic organism of Invention II is not used in any one of the methods of Inventions IV-IX and therefore is patentably distinct therefrom.

Invention III and Invention IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product

(MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in the detection of protein.

The antibody of Invention III is not used in the methods of IV-VIII and is therefore patentably distinct therefrom.

The methods of Inventions IV-IX require different products and/or steps and have different endpoints. Therefore, Inventions IV-IX are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 703-308-0034. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER